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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,169	04/27/2005	Andrew David Bacon	Q85454	9237

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,169	BACON ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 17-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 8-8-06 has been entered. Claims 13 and 16 have been amended. Claim 25 has been added. Claims 1-25 are pending. Claims 13-16 and 25 are under consideration.

It should be noted that examiner for the instant application has been changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-16 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 8-8-06 necessitates this new ground of rejection.

The phrase "a composition for the co-delivery to a cell of a nucleic acid and an assistor protein comprising vesicles formed of amphiphilic components" in claim 13 is vague and renders the claim indefinite. It is unclear what comprises vesicles, it is unclear whether it is the assistor protein or the composition. Claims 14-16 and 25 depend from claim 13.

The phrase "the composition comprising said nucleic acid and said assistor protein associated with the same vesicles as one another" in claim 13 is vague and renders the claim indefinite. It is unclear what is associated with the same vesicle, the composition or said assistor

protein. It is also unclear what the phrase "associated with the same vesicles **as one another**" means. It is unclear whether the component is associated with the same vesicle as an integrated same one or as independent separate ones. Claims 14-16 and 25 depend from claim 13.

The term "derived from" in claim 13 and 25 is vague and renders the claim indefinite. It is unclear as to the metes and bounds of what would be considered "derived from". The term "derived from" can mean any type of modification, such as chemical, conformational, and physical modification, or no modification at all. It is unclear to what extent is meant to be "derived from". Claims 14-16 depend from claim 13.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 16 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating an immune response in a mammal by administering to the mammal a liposomal composition comprising a nucleic acid encoding an antigenic protein and an assistor protein that shares at least one epitope with said antigenic protein, wherein said method confers immunity against infection by an infectious virus corresponding to said antigenic antigen and assistor protein, does not reasonably provide enablement for a method of generating an immune response in a mammal by administering to the mammal the liposomal composition as set forth above, wherein said method confers immunity against infection by any infectious virus. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant's arguments filed 8-8-06 have been fully considered but they are not persuasive.

Applicants argue that the specification is enabling for the entire scope of claim 16, and complete immunity is not required. The example shown in the specification demonstrates statistically significant immune response against a sufficient portion of the population tested. Applicants further argue that the specification provides result viral components other than an influenza virus, such as Hepatitis B, provide a level of immune response consistent with the level of immune response shown for influenza (amendment, p. 11-12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 3-8-06 and the following reasons. Although administration of a liposomal composition, comprising a nucleic acid encoding an antigenic protein and an assistor protein that shares at least one epitope with said antigenic protein, to a mammal may confer immunity against infection by an infectious virus corresponding to said antigenic antigen and assistor protein, however, there is no evidence of record that administration of a nucleic acid encoding an antigenic protein and an assistor protein from a particular infectious microorganism can confer immunity to numerous different viral infection. The claim encompasses using a nucleic acid encoding an antigenic protein and an assistor protein derived from any infectious microorganism, such as parasite, bacteria, and virus etc., to provide immunity to infection by any infectious virus. The specification fails to provide adequate guidance and evidence for how to provide immunity to any infectious virus by using a particular antigen derived from a particular infectious microorganism. One skilled in the art at

the time of the invention would require undue experimentation to practice over the full scope of the invention claimed. Thus, claim 16 remains rejected under 35 U.S.C. 112 first paragraph.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 13-16 remain rejected and the newly added claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Craig, et al., 1997 (WO 97/28818) and is repeated for the reasons set forth in the preceding Official action mailed 3-8-06. Applicant's arguments filed 8-8-06 have been fully considered but they are not persuasive.

Applicants argue that Craig does not relate to delivery system of both peptide and nucleic acid and does not relate to associating both a peptide and a nucleic acid with a liposome. Applicants cite page 24, line 30 to page 25, line 11 of Craig and argue that there is no description regarding peptide antigen associating with liposome (amendment, p. 14). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 3-8-06. Craig teaches administering a mixture to a mammal to elicit an immune response in said mammal, wherein the mixture includes a nucleic acid encoding a first epitope and a peptide containing a second epitope such that both of the nucleic acid and the second epitope are taken up by the antigen presenting cell of the mammal (e.g. abstract). Therefore, Craig does teach delivery system of both peptide and nucleic acid. Craig teaches non-viral delivery means to deliver

nucleic acid and an antigenic peptide or protein associated with nucleic acid to a mammal cell, wherein the non-viral delivery means include DNA/polycation complexes, self assembling virus like particles, and microsphere which are used for delivery of DNA or protein to cells, e.g. polyactide glycolide polymers, and **liposomes** (e.g. p. 12, lines 10-25). Therefore, Craig does teach associating both a peptide and a nucleic acid with a liposome.

Applicants cite page 4, lines 29-35, page 56, lines 12-19, and page 58, lines 27-38, and argue that Craig does not teach that the antigenic protein encoded by the nucleic acid and the assistor protein share the same epitope or are the same protein (amendment, p. 15). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 3-8-06. Craig teaches "[i]n the simplest form, the peptide antigen and the nucleic acid encoded antigen described here are the same" (e.g. p. 17, lines 4-5). Thus, Craig does teach that the antigenic protein encoded by the nucleic acid and the assistor protein share the same epitope or are the same protein.

Applicants cite example 1 and argue that the claimed method provides unexpected results over both Probst and Craig. Example 1 shows liposomally co-entrapped nucleic acid and assistor protein results in higher immune response as compared to non-liposomally co-entrapeed (amendment, p. 15-16). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 3-8-06. Craig teaches delivering a nucleic acid encoding an antigenic protein and a peptide antigen via liposome and states that "it is believed that a more effective immune response may be obtained using a first peptide antigen in combination with a second different nucleic acid-encoded antigen, or wherein several different peptide antigen are administered in combination with one or several different nucleic acid-encoded antigens. A

"more effective" immune response will be evidence, as it relates to prior art vaccination procedures and compositions, as two-fold and preferably a five-fold to ten-fold higher immune response, or by the finding that both a cellular and a humoral immune response is elicited by complexes or mixtures of the invention" (e.g. p. 17, lines 4-18). It appears that it is inherent that combination of a peptide antigen and a nucleic acid encoding an antigenic protein would provide higher immune response in a host via liposomal delivery than the peptide antigen or the nucleic acid alone. Further, the claims do not recite that the claimed method could result in higher immune response than any other combination of delivery system. Thus, claims 13-16 remain rejected and the newly added claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Craig.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 13-16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Probst et al., 2000 (US Patent No. 6,166,177) in view of Gregoriadis et al., 1999 (Methods, Vol. 19, p. 156-162, IDS). Applicants' amendment filed 8-8-06 necessitates this new ground of rejection.

Claims 13-16 and 25 are directed to a method of generating an immune response in a mammal by administering to the mammal a composition comprising a nucleic acid encoding an antigenic protein or portion thereof and an assistor protein that shares at least one epitope with said antigenic protein, wherein the nucleic acid and assistor protein are associated with a liposome for delivery. Claims 14 and 15 specify the immune response comprises an antibody response specific to the antigenic protein and/or assistor protein, and involve stimulation of cytotoxic T-lymphocytes, respectively. Claim 16 specifies the method confers immunity against infection by an infectious virus. Claim 25 specifies the antigenic protein is derived from Hepatitis virus.

Probst teaches using a compound for the treatment of Chlamydial infection, and said compound comprises polypeptides that contain at least one antigenic portion of a Chlamydial antigen and DNA sequence encoding such polypeptides (e.g. abstract). Probst also teaches the polypeptide or DNA molecule is generally within a vaccine, wherein the vaccine may comprise a liposome (e.g. column 8, lines 15-27). A DNA vaccine can be administered simultaneously with or sequentially to either a polypeptide or a known Chlamydia antigen (e.g. column 8, lines 52-55).

Probst does not specifically teach administering both a nucleic acid encoding an antigenic protein and an assistor protein to stimulate immune response via liposome.

Gregoriadis teaches that liposomes are carriers of peptide, protein and DNA vaccines. Gregoriadis teaches techniques that can generate liposomes of various sizes containing soluble antigens as well as antigen-encoding DNA vaccine (e.g. abstract).

It would have been obvious for one of ordinary skill in the art at the time of the invention to administer both a nucleic acid encoding an antigenic protein and an assistor protein to stimulate immune response via liposome because Probst teaches a DNA vaccine can be administered simultaneously with either a polypeptide or a known Chlamydia antigen to stimulate an immune response and Gregoriadis teaches that liposomes are known to be carriers of peptide, protein, and DNA vaccines, and the4 generation of liposomes containing both soluble antigens and antigen-encoding DNA vaccine. It would be inherent or obvious to one of ordinary skill in the art that administration of a vaccine containing a nucleic acid encoding an antigenic protein and an assistor protein would stimulate immune response comprises an antibody response, involves stimulation of cytotoxic T-lymphocytes or confers immunity.

One having ordinary skill in the art at the time the invention was made would have been motivated to do so in order to simulate immune response or for the treatment of Chlamydia infection as taught by Probst with reasonable expectation of success.

Conclusion

No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER